

**K141004 INTRAOSSEOUS FIXATION SYSTEM**Aug 21, 2014  
125 days to decisionK141004 · Product code: **HTY** · Orthopedic  
Source: <https://www.510kdatabase.net/k141004/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Apr 18, 2014
Decision date	Aug 21, 2014
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orthohelix Surgical Designs, Inc.</b>
Location	Cleveland, OH, US
Contact	BRIAN HOCKETT
510(k) history	25 submissions · 25 cleared · 2005-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k141004/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 17, 2026